

Claim 53 (Reiterated) A method to regulate an immune response in a canid, said method comprising administering to said canid a therapeutic composition of Claim 51.

Claim 54 (Reiterated) A method to produce a canine IL-13R α protein, said method comprising culturing a cell capable of expressing said protein.

REMARKS

Claims 1-23, 26, 27, 31-33, 41, 42, 48, 52, 55-59 have been canceled. Claims 30, 36, 44-47, 50 and 51 have been amended to comply with the election of Group I for further prosecution. Applicants note that these amendments merely cancel Claims not falling within Group I and amend the remaining Claims to remove SEQ ID NO's not falling within Group I. Accordingly, Applicants contend no new matter has been entered into the Application.

I. Restriction Requirement - Election of group and species

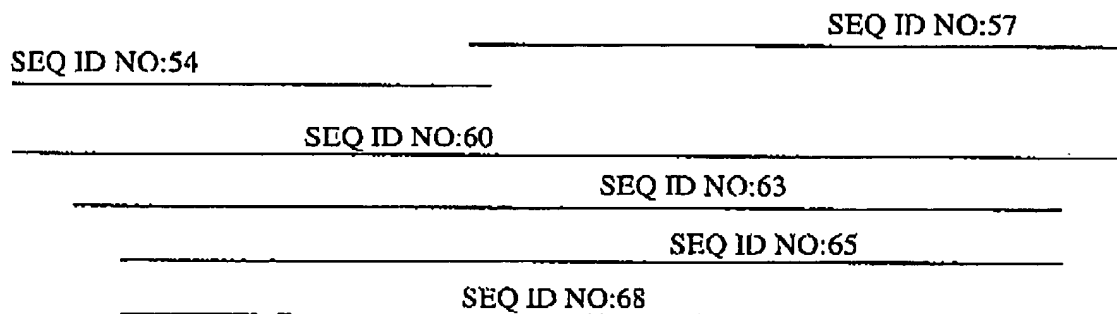
In response to the Restriction Requirement dated July 11, 2002, Applicants elect to prosecute Group I. Additionally, with regard to election of species, Applicants elect to prosecute species (c), IL-13R α 2. Applicants note these elections are made solely in the interest of expediting prosecution of this Application and Applicants reserve the right to traverse division between Groups II-X and division between species in subsequent divisional filings. Applicants also reserve the right to file divisional Applications relating to these claims without the need to file a terminal disclaimer.

II. Restriction Requirement - Election of nucleic acid molecules

The Examiner has further required Applicants to elect a nucleic acid molecule and corresponding protein sequence from Group A that consists of SEQ ID NO:1-70, 72, 75, 78 and 81. Applicants provisionally elect SEQ ID NO:68 with traverse for the following reasons:

Applicants have elected to prosecute nucleic acid molecules relating to the canine IL-13R α 2 protein. Sequences in the Application relevant to IL-13R α 2 include the nucleic acid sequences of SEQ ID NO's 54-57, 59, 60, 62-65, 67, 68, 70, 71, 73, 74, 76, 77, 79, 80, 82 and the

related protein sequences, SEQ ID NO's 55, 58, 61, 66, 69, 72, 75, 78 and 81. The Examiner has stated that each of these sequences is distinct from the other and is a separately patentable sequence that requires a unique search of the prior art. Applicants respectfully disagree noting that all of the sequences listed above are either entirely or partially identical in their regions of overlap since they all relate to the same parent sequence. SEQ ID NO:60, the longest of the sequences, is the sequence of the full length cDNA molecule encoding canine IL-13R α 2 while SEQ ID NO: 62 is the complement and SEQ ID NO:61 the translation. The remainder of the sequences represented by SEQ ID NO:54-70 are either sequence fragments of SEQ ID NO: 60 or the complement or translation of such fragments. When aligned, it can be seen that all of these sequences are identical, over their entire length, with some region of SEQ ID NO:60. A schematic representation of the relationships of these sequences is provided below for the Examiner's convenience:



In addition, SEQ ID NO's 71-82 represent the sequences of hybrid molecules in which a nucleic acid sequence of canine IL-13R α 2 (SEQ ID NO:68) has been linked to the nucleic acid sequence of canine immunoglobulin gamma chain. In all of these hybrid molecules, at least half of the molecule consists of the sequence of SEQ ID NO:68 while the remainder consists of closely related canine IgG sequences. Moreover, it is to be noted that the IgG regions of the four hybrid molecules share a degree of identity ranging from 85-97%.

The Patent Office may require restriction if two or more "independent and distinct" inventions are claimed in one application. However, "if the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." M.P.E.P Section 803. In

the present Application, the sequences represented by SEQ ID NO's 54-70 are identical so that a search done for one sequence would suffice for the entire group. Additionally, the sequences of the fusion molecules, SEQ ID NO's 71-82, are closely related to the IL-13R α 2 sequences and highly homologous to each other, as stated above, and any search performed for one hybrid sequence will necessarily be sufficient for the others. Because of the high degree of identity and the small size of the group to be Examined, Applicants submit that SEQ ID NO's 54-82 can be examined together without serious burden to the Examiner. Therefore, Applicants request withdrawal of the requirement to elect a single nucleic acid sequence.

Respectfully submitted,

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VERSION WITH MARKINGS SHOWING CHANGES

Claims 1-23, 26, 27, 31-33, 41, 42, 48, 52, 55-59 have been canceled.

Claims 24, 25, 28, 29, 34, 35, 37-40, 43, 49, 53 and 54 have been reiterated for the Examiners convenience.

Claims 30, 36, 44-47, 50 and 51 have been amended as follows:

Claim 24. (Reiterated) An isolated nucleic acid molecule selected from the group consisting of:

(a) a first nucleic acid molecule having at least 40 contiguous nucleotides identical in sequence to at least 40 contiguous nucleotide region of SEQ ID NO:54, SEQ ID NO:56, SEQ ID NO:57, SEQ ID NO:59, SEQ ID NO:60, SEQ ID NO:62, SEQ ID NO:63, SEQ ID NO:64, SEQ ID NO:65, SEQ ID NO:67, SEQ ID NO:68 or SEQ ID NO:70; and

(b) a second nucleic acid molecule comprising a first nucleic acid sequence that is at least 80% identical in sequence to SEQ ID NO:54, SEQ ID NO:56, SEQ ID NO:57, SEQ ID NO:59, SEQ ID NO:60, SEQ ID NO:62, SEQ ID NO:63, SEQ ID NO:64, SEQ ID NO:65, SEQ ID NO:67, SEQ ID NO:68 and SEQ ID NO:70, and a fragment thereof, wherein said fragment is at least 50 nucleotides in length, and wherein said percent identity can be determined by a DNAsis™ computer program with a gap penalty set at 5, the number of top diagonals set at 5, a fixed gap penalty set at 10, a k-tuple set at 2, a window size set at 10 and a floating gap penalty set at 10.

Claim 25 (Reiterated) The nucleic acid molecule of Claim 24, wherein said isolated nucleic acid molecule encodes a protein comprising an amino acid sequence selected from the group consisting of SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66 and SEQ ID NO:69.

Claim 28 (Reiterated) An isolated nucleic acid molecule selected from the group consisting of:

(a) a first nucleic acid molecule comprising a first nucleic acid sequence encoding a first protein selected from the group consisting of:

(i) a second protein comprising an amino acid sequence that is at least 70 percent identical in sequence to SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66, and SEQ ID NO:69, wherein percent identity is determined by a DNAsis™ computer program with a gap penalty set at 5, the number of top diagonals set at 5, a fixed gap penalty set at 10, a k-tuple set at 2, a window size set at 10 and a floating gap penalty set at 10; and

(ii) a second protein comprising a fragment of at least 40 contiguous amino acids identical in sequence to an at least 40 contiguous amino acids of the first protein;

(b) a second nucleic acid molecule comprising a second nucleic acid sequence encoding a protein that comprises an at least 30 contiguous amino acid region identical in sequence to an at least 30 contiguous amino acid region of SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66, and SEQ ID NO:69;

(c) a third isolated nucleic acid molecule complementary to the first or second nucleic acid molecule.

Claim 29 (Reiterated) The nucleic acid molecule of Claim 28, wherein said protein binds to canine IL-13, as measured by its ability to inhibit IL-13-stimulated TF-1 cell proliferation.

Claim 30 (Once amended) The nucleic acid molecule of Claim 28, wherein said isolated nucleic acid molecule comprises a nucleic acid sequence that encodes an IL-13R[α]2 protein of at least 40 amino acids in length, wherein said nucleic acid sequence comprises an at least 120 contiguous nucleotide sequence identical in sequence to an at least 120 contiguous nucleotide region of SEQ ID NO:54, SEQ ID NO:56, SEQ ID NO:57, SEQ ID NO:59, SEQ ID NO:60, SEQ ID NO:62, SEQ ID NO:63, SEQ ID NO:64, SEQ ID NO:65, SEQ ID NO:67, SEQ ID NO:68 or SEQ ID NO:70, wherein said isolated nucleic acid molecule does not hybridize under conditions comprising hybridization at 65°C in 0.1 X SSC followed by washing at 65°C in 0.1 X SSC with the third nucleic acid sequence selected from the group consisting of SEQ ID NO:95, SEQ ID NO:96, SEQ ID NO:97 and SEQ ID NO:98.

Claim 34 (Reiterated) An isolated protein selected from the group consisting of:

(a) a first protein comprising a first amino acid sequence of at least 30 amino acids in length, wherein said first amino acid sequence has at least 30 contiguous amino acid region identical in sequence to at least 30 contiguous amino acid region of SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66, or SEQ ID NO:69; and

(b) a second protein comprising a third amino acid sequence that is at least 70 percent identical in sequence to SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66, or SEQ ID NO:69, and a fragment thereof, wherein said fragment is at least 40 amino acids in length, wherein percent identity is determined by a DNAsis™ computer program.

Claim 35 (Reiterated) The isolated protein of Claim 34, wherein said first protein is encoded by a nucleic acid molecule comprising an at least 90 contiguous nucleotide region identical in sequence to an at least 90 contiguous nucleotide region of SEQ ID NO:54, SEQ ID NO:57, SEQ ID NO:60, SEQ ID NO:63, SEQ ID NO:65 or SEQ ID NO:68.

Claim 36 (Once amended) A chimeric nucleic acid molecule encoding a fusion protein comprising:

- (a) a nucleic acid molecule encoding a carrier protein domain; and
- (b) a nucleic acid molecule encoding a canine IL-13R α 2 protein domain.

Claim 37 (Reiterated) The chimeric nucleic acid molecule of Claim 36, wherein said fusion protein further comprises a linker sequence.

Claim 38 (Reiterated) The chimeric nucleic acid molecule of Claim 36, wherein said carrier protein domain is an immunoglobulin Fc region.

Claim 39 (Reiterated) The chimeric nucleic acid molecule of Claim 36, wherein said carrier protein domain is a canine immunoglobulin Fc region.

Claim 40 (Reiterated) The chimeric nucleic acid molecule of Claim 36, wherein said carrier protein domain is a canine immunoglobulin IgG Fc region.

Claim 43 (Reiterated) The chimeric nucleic acid molecule of Claim 36, wherein said chimeric nucleic acid molecule comprises a nucleic acid sequence selected from the group consisting of SEQ ID NO:71, SEQ ID NO:74, SEQ ID NO:77, SEQ ID NO:80 and SEQ ID NO:82.

Claim 44 (Once amended) The chimeric nucleic acid molecule of Claim 36, wherein said nucleic acid molecule encoding said IL-13R α 2 protein domain comprises a nucleic acid sequence selected from the group consisting of [SEQ ID NO:48, SEQ ID NO:49, SEQ ID NO:52,] SEQ ID NO:54, SEQ ID NO:57, SEQ ID NO:60, SEQ ID NO:63, SEQ ID NO:65, and SEQ ID NO:68.

Claim 45 (Once amended) The chimeric nucleic acid molecule of Claim 36, wherein said chimeric nucleic acid molecule comprises said nucleic acid molecule encoding said carrier protein domain on the 5' end of said chimeric nucleic acid molecule and said nucleic acid molecule encoding said IL-13R α 2 protein domain on the 3' end of said chimeric nucleic acid molecule.

Claim 46 (Once amended) The chimeric nucleic acid molecule of Claim 36, wherein said chimeric nucleic acid molecule comprises said nucleic acid molecule encoding said IL-13 α 2 protein domain on the 5' end of said chimeric nucleic acid molecule and said nucleic acid molecule encoding said carrier protein domain on the 3' end of said chimeric nucleic acid molecule.

Claim 47 (Once amended) A fusion protein comprising [(a)] a carrier protein domain[;] and [(b)] a canine IL-13R α 2 protein domain.

Claim 49 (Reiterated) The fusion protein of Claim 47, wherein said fusion protein comprises an amino acid sequence selected from the group consisting of SEQ ID NO:72, SEQ ID NO:75, SEQ ID NO:78, and SEQ ID NO:81.

Claim 50 (Once amended) The fusion protein of Claim 47, wherein said IL-13R α protein domain comprises an amino acid sequence selected from the group consisting of [SEQ ID NO:50,] SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66, and SEQ ID NO:69.

Claim 51 (Once amended) A therapeutic composition that, when administered to a canid, regulates an immune response in said canid, said therapeutic composition comprising a nucleic acid molecule encoding a therapeutic compound selected from the group consisting of:

- (a) a protein selected from the group consisting of a canine IL-13R α 2 and the fusion protein of claim 47;
- (b) a mimotope of said protein; and
- (c) a multimeric form of said protein[;
- (d) an isolated nucleic acid molecule encoding the protein of (a), (b), or (c);
- (e) an antibody that selectively binds the protein of (a), (b) or (c); and
- (f) an inhibitor identified by its ability to inhibit the activity of the protein of (a), (b) or (c)].

Claim 53 (Reiterated) A method to regulate an immune response in a canid, said method comprising administering to said canid a therapeutic composition of Claim 51.

Claim 54 (Reiterated) A method to produce a canine IL-13R α protein, said method comprising culturing a cell capable of expressing said protein.